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Amendment
Attorney Docket No. S63.2R-9493-US02

Remarks

This Amendment is in response to the Office Action dated **December 3, 2004** in which claims 1-3 and 5-15 were rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 6,143,022 ("Shull") in view of U.S. Patent No. 4,950,227 ("Savin"). Claim 4 was rejected under 35 U.S.C. 103 as being unpatentable over U.S. Patent No. 6,270,523 ("Herweck") in view of Savin.

Claim Rejections—35 U.S.C. § 103

As stated in the Office Action in paragraph 2, the Examiner admits that Shull fails to disclose a catheter having sleeves for delivering a stent. The Examiner uses the Savin reference to provide disclosure for a stent delivering system including sleeves for securing and maintaining a reduced diameter of a self-expanding stent on a balloon for delivering to a deployment site. Claims 1-3 and 5-15 were rejected under 35 U.S.C. § 103 as being unpatentable over Shull in view of Savin.

It is impermissible to use hindsight, rather than a teaching, suggestion, or motivation, to modify references for the purpose of rejecting as obvious under 35 U.S.C. § 103. *W.L. Gore & Associates v. Garlock, Inc.*, 721 F.2d 1540, 1553, 220 USPQ 303, 313 (Fed. Cir. 1983). As presented previously, the Federal Circuit has made it plain that the showing of a motivation to combine two or more references must be "clear and particular". See for example *Winner International Royalty Corp. v. Wang*, 53 USPQ2d 1580, 202 F3d 1340 (Fed. Cir. 2000).

The Examiner reviewed Applicants' arguments regarding the lack of motivation to combine the references but did not find them persuasive. Instead, the Examiner cites *In re Fine*, arguing that a prima facie case of obviousness has been established from "generally available knowledge that would lead one skilled in the art to combine teachings of existing

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references.” The Examiner argues that one of ordinary skill in the art would combine sleeves with a membrane because together they would secure the stent to the delivery system and maintain a reduced diameter. The Examiner has, however, failed to provide any “clear and particular” motivation to combine the reference, as required by the Federal Circuit in *Winner International Royalty Corp.* “The showing of a motivation to combine must be clear and particular, and it must be supported by actual evidence.” *Teleflex, Inc. v. Ficosa North America Corp.*, (Fed. Cir. 2002, *en banc*) 299 F.3d 1313, 63 U.S.P.Q.2d 1374. The actual evidence must be “objective evidence of record.” *In re Lee*, 277 F.3d 1338, 61 USPQ2d 1340. Merely asserting that a particular combination of elements from prior art references can be combined to produce the present invention does not provide the required “clear and particular” motivation necessary to support an obviousness rejection.

Applicants respectfully submit that the Examiner has failed to meet the burden set forth under *Winner International Royalty Corp* and therefore respectfully traverse the rejections of claims 1-3 and 5-15.

In the Office Action in paragraph 3, claims 8 and 12 were rejected. Claim 8 depends from nonobvious independent claim 1. For at least the reasons presented above, claim 8 is nonobvious. Also, claim 8 includes a further limitation that “the at least one membrane is water soluble.” The Examiner fails to provide any reference to support the assertion that stent coverings that include a water-soluble drug are well-known in the art. Therefore, Applicants request that the rejection be removed and claim 8 be allowed.

Applicants respectfully traverse the obviousness rejection of independent claim 12. As stated in the Office Action in paragraph 2, the Examiner admits that Shull fails to disclose a catheter having sleeves for delivering a stent. The Examiner uses the Savin reference

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to provide disclosure for a stent delivering system including sleeves for securing and maintaining a reduced diameter of a self-expanding stent on a balloon for delivering to a deployment site. As argued above, there is no teaching, suggestion, or motivation to combine Shull with Savin or Savin with Shull to produce a device with both at least one sleeve and at least one membrane. Furthermore, there is no teaching, suggestion, or motivation to use at least one membrane as a drug delivery device, a further limitation provided in claim 12. It is impermissible to use hindsight, rather than a teaching, suggestion, or motivation, to modify references for the purpose of rejecting as obvious under 35 U.S.C. § 103. The Examiner has failed to provide any "clear and particular" motivation to combine the reference, as required by the Federal Circuit in *Winner International Royalty Corp.* Therefore, Applicants respectfully request that the Examiner withdraw the rejection to claim 12.

In the Office Action in paragraph 4, claim 4 was rejected under 35 U.S.C. 103 as being unpatentable over Herwick in view of Savin. The Examiner admits that Herwick fails to disclose a catheter having sleeves for delivering a stent. The Examiner uses the Savin reference to provide a disclosure for a stent delivery system including sleeves for securing and maintaining a reduced diameter of a self-expanding stent on a balloon. However, this combination is improper because there is no suggestion or motivation to combine Herwick with Savin. Furthermore, the Herwick reference teaches away from the present invention. While the membrane of the present invention is used to prevent flaring (page 9, lines 15-18), Herwick is used to create flaring. (Herwick, col. 6, lines 28-33). Therefore, one of ordinary skill in the art would not look to Herwick to solve the problem of flaring, as accomplished by the present invention.

The Herwick reference teaches using membranes of varying resistances in order to

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prevent the expansion of portions of a stent. (Herwick, col. 6, lines 15-17). Sleeves, on the other hand, are used in order to control delivery of a stent. That is, when the stent delivery system is in place, the sleeves retract, thereby allowing the stent to expand. One of ordinary skill in the art would not combine Herwick, which seeks to prevent expansion of portions the stent, with the sleeves of Savin, which seek to allow expansion of the entire stent upon their retraction.

Conclusion

Claims 1-5 and 7-15 as amended or previously presented, and new claim 16, are believed to be in condition for allowance in view of the foregoing. Applicants respectfully requests that the rejections be withdrawn and that claims 1-5 and 7-16 be allowed. Applicants respectfully request that the amendment be entered which Applicants believe puts the application in condition for allowance or better form for appeal. Early action to that effect is earnestly solicited.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

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By: _____

Richard A. Arrett

Registration No.: 33153

6109 Blue Circle Drive, Suite 2000
Minnetonka, MN 55343-9185
Telephone: (952) 563-3000
Facsimile: (952) 563-3001

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